

Food and Drug Administration, HHS

§ 179.26

(iii) The maximum energy of X-radiation emitted by machine source.

(iv) The minimum and maximum energy of radiation emitted by neutron source.

(2) The label or accompanying labeling shall bear:

(i) Adequate directions for installation and use.

(ii) A statement that no food shall be exposed to radiation sources listed in paragraph (a) (1) and (2) of this section so as to receive an absorbed dose in excess of 10 grays.

(iii) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(3) of this section so as to receive an absorbed dose in excess of 2 milligrays.

(iv) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(4) of this section so as to receive a dose in excess of 0.5 gray (Gy).

(v) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(5) of this section so as to receive a dose in excess of 0.01 gray (Gy).

[42 FR 14635, Mar. 15, 1977, as amended at 48 FR 46022, Oct. 11, 1983; 61 FR 14246, Apr. 1, 1996; 64 FR 69191, Dec. 10, 1999; 66 FR 18539, Apr. 10, 2001; 69 FR 76404, Dec. 21, 2004]

§ 179.25 General provisions for food irradiation.

For the purposes of § 179.26, current good manufacturing practice is defined to include the following restrictions:

(a) Any firm that treats foods with ionizing radiation shall comply with the requirements of part 110 of this chapter and other applicable regulations.

(b) Food treated with ionizing radiation shall receive the minimum radiation dose reasonably required to accomplish its intended technical effect and not more than the maximum dose specified by the applicable regulation for that use.

(c) Packaging materials subjected to irradiation incidental to the radiation treatment and processing of pre-packaged food shall be in compliance with § 179.45, shall be the subject of an exemption for such use under § 170.39 of this chapter, or shall be the subject of an effective premarket notification for

a food contact substance for such use submitted under § 170.100 of this chapter.

(d) Radiation treatment of food shall conform to a scheduled process. A scheduled process for food irradiation is a written procedure that ensures that the radiation dose range selected by the food irradiation processor is adequate under commercial processing conditions (including atmosphere and temperature) for the radiation to achieve its intended effect on a specific product and in a specific facility. A food irradiation processor shall operate with a scheduled process established by qualified persons having expert knowledge in radiation processing requirements of food and specific for that food and for that irradiation processor's treatment facility.

(e) A food irradiation processor shall maintain records as specified in this section for a period of time that exceeds the shelf life of the irradiated food product by 1 year, up to a maximum of 3 years, whichever period is shorter, and shall make these records available for inspection and copy by authorized employees of the Food and Drug Administration. Such records shall include the food treated, lot identification, scheduled process, evidence of compliance with the scheduled process, ionizing energy source, source calibration, dosimetry, dose distribution in the product, and the date of irradiation.

[51 FR 13399, Apr. 18, 1986, as amended at 67 FR 9585, Mar. 4, 2002; 67 FR 35731, May 21, 2002]

§ 179.26 Ionizing radiation for the treatment of food.

Ionizing radiation for treatment of foods may be safely used under the following conditions:

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of the radionuclides cobalt-60 or cesium-137.

(2) Electrons generated from machine sources at energies not to exceed 10 million electron volts.

(3) X rays generated from machine sources at energies not to exceed 5 million electron volts (MeV), except as